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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/006,796

Applicant(s)

PIRHONEN ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 115 6) ☐ Other: ____

DETAILED ACTION

Acknowledgement of Papers Received: Information Disclosure Statement dated 3/6/02 and Supplemental Information Disclosure Statement dated 6/6/03.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9, 11, 13-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al (WO 91/01126). Claims 1-5, and 8 are drawn to a biodegradable implant comprising a polymeric matrix and a plasticizer. Subsequent claims limit the polymer to biodegradable polymers such as polycarbonates, polyurethanes and polyfumarates. The plasticizer is recited to be N-methyl-2-pyrrolidone. Claims 9, 11, 13, 14, 15, and 17 are drawn to a method of manufacturing the implant of claims 1-5, and 8 comprising selecting a polymer, mixing it with the plasticizer and forming the implant. The claims recite the plasticizer can be added either before or after the implant is formed. Also that the plasticizer exists the implant once implanted. Also the surface of the implant is recited to be porous, while the implant is used for tissue regeneration. The implant further comprising bioactive compounds.

Dunn et al discloses biodegradable system for regenerating the periodontium. The implant comprises a polymeric matrix along with various other solvents and components. The polymers are selected from polylactides, polyglycolides, and polyamides (pg. 8, lin. 23 – 38). N-

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methyl-2-pyrrolidone is recited as a solvent in the system (pg. 9, lin. 23 – 25). Once implanted/injected into the body the solvents dissipate leaving a more rigid polymer comprising a porous polymer with bioactive agents such as growth hormones and/or antimicrobial agents lodged within the polymeric matrix (pg. 11, lin. 13 – pg. 12, lin. 8). Since claims 1-8 are drawn to a product is irrelevant the order in which the product is made. Claims 6 and 7 are deemed product-by-process claims and do not impart patentability on the invention. These disclosures along with others render the claims anticipated.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 10,12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al (WO 91/01126). Claims 10, 12, are drawn to methods of manufacture where the

plasticizer is added to the implant after the implant is formed. Claim 16 is drawn to a method where the plasticizer is mixed with the active agent, then mixed with the polymer.

As discussed above Dunn et al discloses many of the essential elements of the invention. Dunn discloses a biodegradable implant used for rebuilding tissue, where the implant comprises N-methyl-2-pyrrolidone, which dissipates from the implant upon placement in the body. What is lacking however is an explicit disclosure to the differing order of manufacture recited by applicant. It is the position of the examiner that these claims are non critical to the patentability of the invention. Dunn presents an identical product made with identical components, used for the same purpose of regenerating tissue. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

It would be within the level of skill in the art to manipulate the order of the procedure, in order to determine the most effective manufacturing method. This can be accomplished through routine experimentation in the art. With this in mind, it would have been obvious to one of ordinary skill in the art to follow the teachings and suggestions of Dunn in order to rebuild periodontal tissue after surgery. A skilled artisan would have expected to attain a porous,

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biodegradable implant useful in rebuilding periodontal tissue after dental surgery. The bioactive agents in the implant would help treat any possible infections, during the healing process.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yoon et al (USPN 5,948,020) discloses a biodegradable implant comprising N-methyl-2-pyrrolidone and biodegradable polymers. The implant is used to rebuild periodontal tissue after dental surgery.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
July 11, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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